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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,652	04/30/2001	Akihiro Kondo	KONDO 7	1863

1444 7590 12/16/2002

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 12/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,652

Applicant(s)

KONDO ET AL.

Examiner

Suryaprabha Chunduru

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10 and 11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election with traverse of Group I (claims 1-6, 10-11) in Paper No. 10 is acknowledged. The traversal is on the ground(s) that limiting the combination of the gene and the endocrine disruptor used in the claimed method to one specific species combination is not appropriate. This is found not persuasive because election of species under markush group is made for search purposes. It is not intended to limit the claim(s), but rather to permit the examiner to focus and address the issue in order to achieve compact prosecution. Hence the restriction to elect one species combination is deemed proper.
2. The Information Disclosure Statement (Paper No. 9) filed on October 10, 2002 has been entered and considered.
3. The Preliminary Amendment (Paper Nos. 5 and 6) filed on April 30, 2001 has been entered and considered.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-6 and 10-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 5 and 6 are indefinite over the recitation of "potentially influenced" because potentially influenced is a latent characteristic and the claims do not set forth the criteria by which to determine potentiality. That is, it is not clear whether the recited genes have the potential to be influenced or effected by the endocrine disruptor or do in fact are influenced or effected by the to the endocrine disruptor. Amendment of the claim to read

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the phrase properly would obviate this rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 1, 3, 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Adams et al. (USPN. 6,376,169).

Adams et al. teach a method for detecting a gene or a substance (DDT) that is influenced by an endocrine disruptor (see column 2, lines 25-31, column 12, lines 48-67) wherein Adams discloses that the method comprises (a) preparing a nucleic acid sample containing mRNA, or cDNA which has been exposed to an endocrine disruptor (column 12, lines 48-67, column 13, lines 1-5, column 14, lines 13-51); hybridizing the nucleic acid sample hybridized to a DNA probe or gene or genes of interest (array of genes) (see column 9, lines 27-42, column 8, lines 48-54, column 14, lines 52-67, column 15, lines 1-14); detecting the gene by comparing the results with the results from a control or standard sample (see column 9, lines 27-42, column 5,

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lines 57-67); Adams also disclose that the method comprises measuring gene expression (see column 9, lines 27-42); endocrine disruptor as DDT, a phenyl substance (see column 12, lines 48-67). Thus the disclosure of Adams et al. meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 4, 6, 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (USPN. 6,376,169) in view of Kuiper et al. (Endocrinology, Vol. 139, No. 10, pp. 4252-4263, 1998).

Adams et al. teach a method for detecting a gene or a substance (DDT) that is influenced by an endocrine disruptor (see column 2, lines 25-31, column 12, lines 48-67) wherein Adams discloses that the method comprises (a) preparing a nucleic acid sample containing mRNA, or cDNA which has been exposed to an endocrine disruptor (column 12, lines 48-67, column 13,

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lines 1-5, column 14, lines 13-51); hybridizing the nucleic acid sample hybridized to a DNA probe or gene or genes of interest (array of genes) (see column 9, lines 27-42, column 8, lines 48-54, column 14, lines 52-67, column 15, lines 1-14); detecting the gene by comparing the results with the results from a control or standard sample (see column 9, lines 27-42, column 5, lines 57-67); Adams also disclose that the method comprises measuring gene expression (see column 9, lines 27-42); endocrine disruptor as DDT, a phenyl substance (see column 12, lines 48-67). However, Adams did not teach nuclear receptor gene as the gene influenced by the endocrine disruptor as phenol substances or compounds.

Kuiper et al. teach a method for interaction of estrogenic chemicals and phytoestrogens with estrogen receptor (a nuclear receptor), wherein Kuiper et al. disclose that the method comprises transient expression of estrogen receptor response element in response to the chemical compounds, which include phenols and phenyl compounds (see page 4254, column 2, paragraph 5, page 4257, column 1, paragraph 2, column 2, paragraphs 1-2, page 4259, column 2, table 3), indicating transcriptional stimulation of suspected endocrine disruptors were mediated by the estrogen receptor (see page 4257, column 2, paragraph 2).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method of detecting a gene influenced by endocrine disruptor as taught by Adams et al. with the method of interaction of chemicals mediating estrogen receptor as taught by Kuiper et al. to achieve expected advantage of developing a sensitive method for detecting gene(s) effected by endocrine disruptor(s) because Kuiper et al. suggests that "transcriptional stimulation observed for suspected endocrine disruptors (which include phenols) was mediated by estrogen receptor" (see page 4257, column

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2, paragraph 2). An ordinary practitioner would have been motivated to combine the method of Adams et al. with the method of Kuiper et al. to improve characterization of endocrine disruptors by incorporating the transcriptional activation of gene mediated by the endocrine disruptors because the effect of a gene or genes influenced by endocrine disruptors would result in a better profile for characterization of an endocrine disruptor compound and its role in the said endocrine metabolic signaling pathway.


Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-305-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
December 10, 2002


JEFFREY FREDMAN
PRIMARY EXAMINER